



NASA Biological Specimen Repository

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NASA's Biological Specimen Repository--NBSR

- A secure storage facility used to maintain a specimen collection for study of human spaceflight-related changes over extended periods of time, under controlled conditions
- Collect, process, annotate, store, and distribute specimens and associated clinical data in a standardized manner in one physical location.
- Supports the Human Research Program, which:
 - Identifies and investigates physiological changes that occur during human spaceflight
 - Develops and implements effective countermeasures when necessary.





Background

- Established in 2007
- Purpose: collect scientific samples on-orbit for future space flight research
- Participants: crew members on the International Space Station.
- Specimen inventory: 6180 samples from 90 USOS crewmembers.
- End date: following the conclusion of Crew-5 and 68S missions



Specimen Collection:

Eight time points for each participant:

- L-3/1
- FD 15
- FD 30
- FD 60
- FD120
- FD 180
- R+3/7
- R+30

- These collections include Blood and Urine samples.
- Blood samples collected in Lithium Heparin and Serum Separator tubes.
- Urine samples combined into 24hr collection pools for total volume prior to aliquoting.



Processing

- Blood and Urine samples are tested prior to storage to provide a baseline for which to assess the quality of the samples once thawed and distributed.
 - Blood is tested for Total Protein, Chloride, Calcium, and BUN
 - Urine is tested for Total Volume, Calcium, Creatinine and Phosphorus
- 500 uL samples are then aliquoted into tubes labeled for Serum, Plasma, and Urine.



Specimen Preservation & Storage

- Avoidance of unnecessary thawing and refreezing of frozen specimens
- Temporary storage in racks at -80 degrees Celsius in Building 21 at JSC
- Samples transfer to the JSC-contracted Conroe storage facility for long term storage.
- Automated security systems to continuously monitor the function of storage equipment.
- Emergency procedures for protection of specimens for environmental, electrical, and equipment failures



Tiered Informed Consent

- Informed consent for the donation of biological specimens to the repository secured separately from consent to the use of these specimens in specific research
- Subjects offered options over the scope of use (tiered consent):
 - Coded or identified use of their biological samples for any human spaceflight-related research study will require their informed consent to release the samples
 - Coded or identified use of their biological samples for any human spaceflight-related research study is permitted and will not require further contact with the individual
 - Exception: Human genetic research (including sequencing of a human germline or somatic specimen with intent to generate the genome or exome sequence) will require an individual's specific consent.



Disposition of specimens

- Procedures for handling and disposition of specimens and associated data for the following:
 - Completion of the specific research objectives of the study
 - Depletion of specimens
 - Achievement of critical data endpoints
- Signed agreement for return of unused portions of specimens to the repository prior to release of the specimens
- Record of sample storage conditions for the unused portions upon return of specimens
- Control of the secondary distribution of specimens (forbids investigator from transferring specimens to third party)



Future Work for Specimen Access

- Implementation of a quality management system to ensure adherence to biorepository standards
- Accreditation of the biorepository (industry standard)
- Development of an application process for the distribution of samples including tracking and status of samples.
- Procedures defining how specimens are de-linked from subject identities (i.e., when, who performs, what identifying information is removed, how)
- Development of an application process for the distribution of samples.
- Peer review process to determine priorities for allocation of specimens to qualified investigators
- Limited to human spaceflight-related studies directly related to the NASA mission
- Establishment of an appeals process addressing disputes over allocation decisions



Specimen Access and Distribution

- Scientific merit of the research proposal
 - Research design, scientific and programmatic relevance
 - Likelihood that the research will provide meaningful results
 - Strong rationale to justify use of rare, limited resource specimens
- Proven investigator experience with the method proposed
- Statistical evaluation which shows that the number of samples requested are adequate to meet the stated aims
- Policies to control the distribution of rare specimens
- Control over the last sample of a particular specimen
- Prevention of the control of an entire specimen or type of specimen by one researcher
- Funding level for project and IRB approval for such funding allocation
- Agreement to make all data freely available to NASA and its designees (and to publish de-identified data so others may have access to the information.)

